

## REMARKS

Claims 1 and 9-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1,4,5-9 and 1113 of copending Application No. 10/814,354. Such rejection is not understood, however, as the Examiner apparently mistakenly references the Serial Number of the present application, rather than that of a copending application. It is noted that the Examiner does subsequently further reference an “ ‘026 application”, and that present application was concurrently filed with two additional applications, USSN 10/815,010 and USSN 10/815,026. To advance prosecution, terminal disclaimers are submitted herewith with respect to each of such copending applications, thus mooted any possible obviousness-type double patenting rejection over these applications. Reconsideration of this rejection is accordingly respectfully requested.

Claims 1, 3 and 5-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saim et al patent 6,858,166 in view of Gurth patent 6,132,080. The Examiner states that Saim et al disclose formation of micro or nano-particles by a process of admitting a supercritical fluid to a vessel, in which temperature and pressure are controlled (column 14, lines 21-45), agitating such vessel with a rotary agitator comprising an impeller of un-specified, given diameter relative to vessel diameter (column 14, line 63column 15, line 6), introducing a 1<sup>st</sup> feed stream comprising a solvent and desired, active substance through a 1<sup>st</sup> introduction port and introducing a 2<sup>nd</sup> feed stream comprising the supercritical fluid through introduction ports both approximately within the vertical alignment of the diameter of the impeller (see especially figures 1 and 2 and column 18, lines 30-63), where particles are precipitated within such vessel over a carrier bed. The Examiner further states that it would have been obvious to one of ordinary skill in the art to have performed the process of Saim using a similar type and diameter of impeller to that of Gurth, so as to create an inward and subsequent outward relatively gentle flow of substances being mixed, so as to effect a more thorough, homogenous mixing, without creating turbulence or other mixing mechanisms that would damage the pharmaceutical substances being mixed. This rejection is respectfully traversed.

As noted by the Examiner, Gurth teaches relatively gentle fluid mixing so as to avoid creating turbulence and damage to delicate materials. Saim discloses introduction of a pressurized gaseous fluid from above an upper surface of a bed of carrier particles in a solute precipitation vessel, and of an organic liquid solution from a level below or slightly above the upper surface of the bed of carrier particles (col. 13, lines 24-28), and mixing of the bed of carrier particles to coat the carrier particles with particles of material precipitated from the solution. As Saim and Gurth are clearly directed towards distinct process, there would be no teaching or suggestion to combine them as proposed by the Examiner.

The present invention is specifically directed towards a process for the formation of particulate material of a desired substance in a particle formation vessel by precipitation from a solution, where feed streams of the solution and of a supercritical fluid are both introduced in a highly agitated turbulent flow zone (see, e.g., page 7, line 31). Claim 1 has been amended to more particularly refer to such turbulent flow feature of the highly agitated zone, in accordance with page 7, line 31 of the specification. As described in the paragraph bridging pages 7-8 of the specification, by introduction of such feed streams into such a zone, along with provision of a bulk mixing zone, it has been found that precipitated particles of size less than 100 nm can advantageously be produced free of large levels of non-uniform large particles. There would be no teaching or suggestion to do so based on Saim, which instead teaches introduction of solution and compressed fluid to distinct areas (i.e., above and below the carrier particle bed), or remote from the mixer (i.e., both above the bed of mixed carrier particles). There would further be no suggestion to do so based on Gurth, which is directed towards non-turbulent gentle mixing. Accordingly, a *prima facie* case of obviousness has clearly not been established, and reconsideration of this rejection is accordingly respectfully requested.

Claims 2 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saim in view of Gurth as applied to claims 1 and 3 above, and further in view of Sievers et al patent 5,639,441. The Examiner states it would have been further obvious to one of ordinary skill in the art to have adapted the Saim process to a balanced continuous flow mechanism, as in Sievers, in order to

manufacture a much greater, industrial quantity of particles, and to have adapted the Sievers back-pressure regulator, in order to effect greater control of uniformity of particle size and processing pressures in the mixing vessel. This rejection is respectfully traversed.

It is initially respectfully urged that Sievers does not overcome the deficiencies of the primary references with respect to the invention of claim 1, and that claims 2 and 4 are patentable thereover for at least the same reasons as explained above. Further, Saim is specifically directed towards the coating of carrier particles loaded in a vessel by precipitation of material onto a bed of such particles. While particles of material to be precipitated may be formed by SAS in at least one of the modes described in Saim, Sievers is directed towards particle formation upon expansion of a pressurized fluid, not in a pressurized particle formation vessel. While Sievers may describe a balanced continuous flow procedure, there is no teaching or suggestion as to how this would be achieved in the batch process of Saim where the bed of carrier particles are to be coated by the precipitated material. Reconsideration of this rejection is accordingly respectfully requested.

In view of the foregoing amendments and remarks, reconsideration of this patent application is respectfully requested. A prompt and favorable action by the Examiner is earnestly solicited. Should the Examiner believe any remaining issues may be resolved via a telephone interview, the Examiner is encouraged to contact Applicants' representative at the number below to discuss such issues.

Respectfully submitted,



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If the Examiner is unable to reach the Applicant(s) Attorney at the telephone number provided, the Examiner is requested to communicate with Eastman Kodak Company Patent Operations at (585) 477-4656.